

**VIRGINIA BOARD OF MEDICINE
AD HOC ON COMPOUNDING COMMITTEE MINUTES**

Thursday, April 13, 2006

Department of Health Professions

Richmond, VA

CALL TO ORDER: The meeting of the Committee convened at 10:12 a.m.

MEMBERS PRESENT: John Armstrong, Chair
James Bowles, Jr., MD
Hugh Bryan, MD
Lee Ann Hansen, Pharm.D
James May, III, MD
David Newton, PhD

MEMBERS ABSENT: Thomas Leecost, DPM, Board President
Richard Ingram, MD
Burton Sundin, MD

STAFF PRESENT: William L. Harp, MD, Executive Director
Ola Powers, Deputy Executive Director - Licensure
Elaine Yeatts, DHP Senior Policy Analyst
Colanthia Morton Opher, Recording Secretary

OTHERS PRESENT: W. Scott Johnson, HDJN
Tyler Cox, Medical Society of Virginia
Michael Jurgensen, Medical Society of Virginia
Winston Trice, MD

Adoption of Agenda

Dr. Bryan moved to adopt the agenda as presented. The motion was seconded and carried.

Approval of the August 16, 2005 Minutes

Dr. Bowles moved to accept the minutes of August 16, 2005. The motion was seconded and carried.

Public Comment on Agenda Items

No public comment was allowed as the period for comment had closed.

As Chair, Dr. Armstrong indicated he would determine if attendees could join in the discussion.

Introduction to the reconvention of the Committee

Dr. Harp reminded the committee that the emergency regulations went into effect December 21, 2005 and will be effective for 12 months. Dr. Harp advised that prior to the expiration date of the emergency regulations, they will need to be replaced by final regulations. Dr. Harp advised the NOIRA published generated considerable comment and the Board of Medicine recommended that the Ad Hoc Committee on Compounding be reconvened to consider the public comment.

The Emergency Regulations and the Notice of Intended Regulatory Action (NOIRA) for final regulations

Ms. Yeatts advised that the comment period on the notice ended February 22, 2006 and the current emergency regulations must be replaced by December 20, 2006. Ms. Yeatts informed the board that the adoption of proposed regulations would be done at the June 22, 2006 and once permission has been given to publish the regulations, there would be a 60-day comment period, public hearing and then the adoption of final regulations would be done at the October 19, 2006 meeting.

Comments received on the NOIRA

Dr. May voiced his concern over the expectation of the committee to adequately discuss and make suggestions on the public comments, stating he did not feel that comments were provided sufficiently early for the committee members to review prior the meeting.

Dr. Armstrong advised the Committee that time would be allowed for the reading of each comment and the issues would be discussed one at a time.

The Committee read and discussed comments from: 1) Mitchell Miller, MD, FAAFP, 2) Jeffrey Schul, MD, AASV, 3) Hugh Bryan, III, MD, 4) Joseph Leming, MD, FAAFP, and 5) Norris Royston, MD, MSV.

Review and revision of the emergency regulations

18VAC85-20-400(A)

Dr. Bryan moved to amend the three occurrences that read ... of less than ~~eight~~ ten hours,... The motion was seconded and carried.

18VAC85-20-400(B)(1)

The Committee unanimously agreed to change the word “sanitization” to *disinfection*.

The following motions were made after committee discussion with attendee input:

Dr. Bryan moved to amend 18VAC85-20-400(B)(1) by changing the word “sanitization” to *disinfection*, and striking the second sentence. The motion was seconded and carried.

Dr. May moved to amend 18VAC85-20-400(B)(1) to reference the definition of aseptic manipulation to USP Chapter 797. The motion was seconded but failed.

Dr. Bryan moved to amend 18VAC85-20-400(B)(1) and strike items (a.) – (f.) and include a new (B)(1) sentence as follows: “*Utilize the practices and principles of disinfection techniques, aseptic manipulations and solution compatibility in immediate-use mixing, diluting or reconstituting;...* . The motion was seconded and carried.

For the purpose of clarification on who is required to have a second check, Dr. Hansen moved to amend 18VAC85-20-400(3) to say, “Establish and *implement* procedures for verification of ... and registered ~~licensed~~ nurse who has been... and add a second sentence stating “*Mixing, diluting or reconstituting that is performed by a doctor or medicine or osteopathic medicine, a pharmacist, or by a specifically trained physician assistant or registered nurse does not require a second check.*”

Dr. Bowles moved to amend 18VAC85-20-400(4) as follows: “... diluted or reconstituted. ~~the date of preparation, and the date of administration(.) as evidence that the mixing, diluting or reconstituting was immediate use.~~ The motion was seconded and carried.

Dr. May moved to amend 18VAC52-400(5) as follows: “...maintain *written policies and procedures* ~~for the procedures~~ to be followed... and striking pursuant to subdivision B 1 of this subsection. The motion was seconded and carried.

There was a brief discussion about the impact of these regulations in 2007.

Dr. Armstrong urged those parties involved to go back to the committee that drafted the legislation to better define the definition of supervision taking into consideration special circumstances such as non-private practice settings.

Adjournment: With no other business to conduct, the meeting adjourned at 1:42 p.m.

John Armstrong, MD
President

William L. Harp, M.D.
Executive Director

Colanthia Morton Opher
Recording Secretary